Pursuant to the authority vested in the Cannabis Control Board by Sections 13 and 91 of the Cannabis Law, Chapter II of Subtitle B of Title 9 of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, and a new Part 114 is added, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Part 114

CANNABINOID HEMP

Part 114 – Cannabinoid Hemp

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Section 114.1 Definitions

For purposes of this Part, the following terms shall have the following meanings:

(a) *Broad spectrum* means hemp extract or cannabinoid hemp product containing multiple cannabinoids, but where Δ9-Tetrahydrocannabinol (THC) has been removed to non-detectable levels using a fit-for-purpose method, with a limit of quantification of less than 0.01% THC.

(b) *Cannabidiol* or *CBD* means the naturally occurring hemp-derived phytocannabinoid cannabidiol, but does not include synthetic cannabidiol.

(c) *Cannabinoids* means any hemp-derived phytocannabinoid, including but not limited to, Tetrahydrocannabinol (THC), tetrahydrocannabinolic acid (THCA), cannabidiol (CBD), cannabidiolic acid (CBDA), cannabinol (CBN), cannabigerol (CBG), cannabichromene (CBC), cannabicyclol (CBL), cannabivarin (CBV), tetrahydrocannabivarin (THCV), cannabidivarin (CBDV), cannabichromevarin (CBCV), cannabigerovarin (CBGV), cannabigerol monomethyl ether (CBGM), cannabielsoin (CBE), cannabicitran (CBT). Cannabinoids do not include synthetic cannabinoids, as that term is defined in subdivision (g) of section 3306 of the Public Health Law and section 9-1.1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York.

(d) *Cannabinoid hemp product* means hemp or any product manufactured or derived from hemp, including hemp derived terpenes, in its final form, used for human consumption. Cannabinoid hemp product shall not include cosmetics.

(e) *Cannabinoid hemp retailer* means a person licensed by the office to sell cannabinoid hemp products, including via the internet, to consumers in New York State.

(f) *Cannabinoid hemp farm processor* means a cannabinoid hemp processor that is licensed to cultivate hemp by the New York State Department of Agriculture & Markets and is permitted to manufacture cannabinoid hemp flower products. A cannabinoid hemp farm processor shall not:

(1) produce more than 1,000 pounds of dried hemp annually;

(2) purchase or sell hemp or hemp extract other than those produced from hemp grown on their own farm; or

(3) perform extraction as defined in subdivision (1) of this section.

(g) Cannabinoid hemp processor means a person licensed by the office to extract hemp extract and/or manufacture cannabinoid hemp products in New York State, whether in intermediate or final form, to be used for human consumption.

(h) *Certificate of analysis* means a certified report from an independent third-party laboratory meeting all of the requirements of section 114.10 of this Part, describing its analytical testing and results.

(i) *Corrective action plan* means a plan submitted by a licensee and approved by the office

under this Part for the licensee to correct a violation or non-compliance with this Part.

(j) *Cosmetic* means a cosmetic meeting the requirements of section 321 of Title 21 of the United States Code and recognized as such by the office.

(k) *Craft means a cannabinoid hemp product manufactured from hemp grown by a licensed hemp grower who grows less than 1,000 pounds of dried hemp annually and the hemp is hand trimmed, hang dried and if a cannabinoid hemp flower product hand packaged.*

(l) *Distillate* means hemp extract where a segment of one or more cannabinoids from an initial extraction are selectively concentrated through heating and cooling, with all impurities removed.

(m) *Distribute* means to offer or sell cannabinoid hemp products to a cannabinoid hemp retailer, for retail sale to consumers within New York state.

(n) *Extract* or *Extraction* means the process of concentrating or isolating one or more cannabinoids from hemp or cannabinoid hemp.

(o*) Flower product* means any form of cannabinoid hemp product consisting of the flower, buds, leaves, or stems of the hemp plant, including trimmings thereof, intended for retail sale to consumers with minimal processing. Provided, however that flower product shall not include:
(1) any food, food ingredient, food additive, or items that are generally recognized as safe, pursuant to state or federal law; or
(2) any other product, including microgreens, sprouts or certain hemp leaf products, as determined by the office.

(p) *Full spectrum* means hemp extract or cannabinoid hemp product containing multiple hemp-derived cannabinoids, terpenes, and other naturally occurring compounds, processed without intentional complete removal of any compound and without the addition of isolated cannabinoids, with a final Δ9-Tetrahydrocannabinol concentration of not greater than 0.3%.

(q) *Hemp* means the plant Cannabis sativa L. and any part of such plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a Δ9-Tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis.

(r) Hemp extract means all derivatives, extracts, cannabinoids, isomers, acids, salts of isomers derived from hemp and used for human consumption, with a Δ9-Tetrahydrocannabinol concentration of not more than an amount determined by the office pursuant to this Part. Hemp extract shall not include:

(1) any food, food ingredient or food additive that is generally recognized as safe pursuant to federal law; or

(2) any extract derived from hemp that is not used for human consumption.

(s) *Isolate* means hemp extract or cannabinoid hemp product comprised of 95 percent or more of a single cannabinoid compound.

(t) *Lot* or *batch* means any cannabinoid hemp product produced during a period of time under similar conditions and identified by a specific code that allows traceability.

(u) *Manufacture* means to prepare, treat, modify, compound, process, package or otherwise manipulate hemp or hemp extract into a cannabinoid hemp product. Manufacturing shall not include:

(1) growing, cultivating, cloning, harvesting, drying, curing, grinding or trimming when authorized pursuant to Article 29-A of the Agriculture and Markets Law; or

(2) extraction as defined in subdivision (l) of this section.

(v) *New York Hemp Product* means a cannabinoid hemp product that is derived from hemp exclusively grown, extracted and manufactured in New York, in compliance with section 114.13 of this Part.

(w) *Person* means an individual, partnership, corporation, limited liability company, association, or any business entity or institution of higher education, by whatever name designated and whether or not incorporated.

(x) *Serious adverse event* means a medical occurrence associated with the use of a cannabinoid hemp product in a human that results in one or more of the following outcomes: death, a life-threatening event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

(y) *Total Δ9-Tetrahydrocannabinol concentration* means + (0.877 x).

(z) *Used for human consumption* means intended by the manufacturer or distributor to be:

(1)used for human consumption for its cannabinoid content; or

(2) used in, on or by the human body for its cannabinoid content.

Section 114.2 Application for cannabinoid hemp processor license.

(a) No person or entity shall extract hemp extract or manufacture cannabinoid hemp product, or hold itself out as a cannabinoid hemp processor, unless it is in compliance with Article 5 of the Cannabis Law and this Part and is licensed by the office as a cannabinoid hemp processor.

(b) An application for licensure shall be submitted to the office on a form prescribed by the office which shall include the following:

(3) the name, address, telephone number and email address of the applicant;

(4) identification of all real property, buildings and facilities that will be used in the extracting of hemp extract or manufacturing of cannabinoid hemp;

(5) the days and hours of operation;

(6) the Federal employer identification number of the applicant;

(7) for applicants extracting hemp extract, identification of all extraction methods that will be used to carry out the extracting;

(8) proof of New York State Workers' Compensation and Disability Insurance coverage, or a Certificate of Attestation of Exemption from coverage;

(9) a summary and description of the applicant's:

(i) source(s) of hemp and hemp extract to be used by the licensee; and

(ii) cannabinoid hemp products to be manufactured;

(10) a statement that the applicant's standard operating procedures will incorporate any language or requirements provided by the office and adequately address quality assurance, security, and a plan to ensure all hemp and hemp extract obtained by the applicant meets the requirements of this Part.

(11) evidence that Good Manufacturing Practices (GMP) will be used in the extraction of hemp extract and manufacturing of cannabinoid hemp products. Such evidence shall include one of the following:

(i) proof of a qualified third-party GMP audit of the applicant's extraction and manufacturing processes; or

(ii) a detailed plan for obtaining a qualified third-party GMP audit within six months of approval of the application and before beginning operations as a cannabinoid hemp processor in New York State;

(12) a copy and description of any other license(s) issued by state or federal authorities related to the operations of the licensee or the facility where licensed activity will occur;

(13) a description of any other businesses or business activities conducted on the premises to be licensed;

(14) copies of the organizational documents of the applicant;

(15) a statement attesting that the applicant and those in control of the entity, meaning a person that has the ability to direct the activity of the applicant or licensee, including principals, officers or others with such control, are of good moral character;

(16) a statement attesting that the applicant will comply with all applicable state and local laws and regulations relating to the activities in which it intends to engage under the license;

(17) a statement attesting that the applicant has the experience and competency to undertake the activities for which licensure is sought; and

(18) any other information as may be required by the office.

(c) The information required by subparagraph (b)(9) of this section shall not be required for cannabinoid hemp farm processors applicants.

(d) Applications under this section shall be accompanied by a non-refundable application fee of $1,000 for extraction and manufacturing, $500 for manufacturing only and $100 for cannabinoid hemp farm processors.

(e) Applicants shall verify the truth and accuracy of the information contained in the application. The office, in its discretion, may reject or deny an application if it determines that information contained therein is false, inaccurate or omits a material fact.

Section 114.3 Application for Cannabinoid Hemp Retail License.

(a) No person shall offer or sell cannabinoid hemp products to consumers in New York State, or hold itself out as a cannabinoid hemp retailer, unless it is in compliance with Article 5 of the Cannabis Law and this Part and is licensed by the office as a cannabinoid hemp retailer.

(b) An application for licensure shall be submitted to the office on a form prescribed by the office, which shall include the following:

(1) the name, address, telephone number and email address of the applicant;

(2) the physical address of any real property where the applicant intends to operate, the days and hours of operation of such retail facility, and for any online retailer, the internet address of the applicant;

(3) the name, and license number to the extent practicable, of the manufacturer, packer, distributor, or cannabinoid hemp processor, and state or country where the manufacturer, packer, or distributor is located, for all cannabinoid hemp products the applicant intends to offer for sale;

(4) a summary and description of the types and forms of cannabinoid hemp products the applicant intends to offer for sale;

(5) a statement attesting that the applicant will not sell inhalable cannabinoid hemp products or flower products to consumers under 21 years of age;

(6) a statement attesting that the applicant and those in control of the entity, meaning a person or persons that have the ability to direct the activity of the applicant or licensee, including principals, officers or others with such control, are of good moral character;

(7) a statement attesting that the applicant will comply with all applicable state and local laws and regulations relating to the activities in which it intends to engage under the license;

(8) a statement attesting that the applicant will not distribute or sell any cannabinoid hemp product in the form of an injectable, inhaler, or flower product clearly labeled or advertised for the purpose of smoking or in the form of a cigarette, cigar or pre-roll or otherwise packaged or combined with other items designed to facilitate smoking such as rolling papers or pipes, or any other disallowed form as determined by the office;

(9) proof of a certificate of authority from the New York State Department of Taxation and Finance, as applicable; and

(10) any other information as may be required by the office.

(c) All applications under this section shall be accompanied by a refundable license fee of $300 for each retail facility to be licensed by the office.

(d) Applicants shall attest to the truth and accuracy of the information contained in the application. The office, in its discretion, may reject or deny an application if it determines that information contained therein is false, inaccurate or omits a material fact.

Section 114.4 License issuance and denial.

(a) An application for licensure under this Part shall only be approved by the office if:

(1) a complete application has been submitted to the office, along with all necessary fees;

(2) the application demonstrates, to the satisfaction of the office, that the applicant will operate in accordance with Article 5 of the Cannabis Law and this Part;

(3) the applicant is ready, willing and able to properly carry on the activities set forth in the application; and

(4) the applicant is of good moral character.

(b) In determining whether to deny a license application, including an application for renewal, the office may consider the following factors with respect to the applicant, its owner(s) and any affiliated person, including parties with a controlling interest:

(1) false representation or omission of a material fact in filing the license application;

(2) failure to supply further information necessary to process the license application, within thirty days of the office's written request, without satisfactory explanation;

(3) conviction of any crime or sustained charges of administrative violations of state or federal laws, rules or regulations, related to the operation of a site growing, extracting, manufacturing or selling cannabis, hemp or cannabinoid hemp, in accordance with Article 23-A of the Correction Law. Convictions qualifying for expungement pursuant to section 160.50 of the Criminal Procedure Law shall not be considered for purposes of this subdivision;

(4) a pattern of deficiencies, including but not limited to:

(i) refusal or inability to produce records or reports as requested by the office;

(ii) failure to correct deficiencies in accordance with an approved corrective action plan;

(iii) deviation from regulations or standard operating procedures so as to jeopardize the quality of hemp extract or cannabinoid hemp products; and

(iv) refusal to provide office employees with access to the premises;

(5) knowledge of sale of cannabinoid hemp products not meeting the requirements of this Part; and

(6) general failure to comply with the requirements of this Part.

(c) Denial of a license shall preclude the applicant from being licensed as a cannabinoid hemp processor or cannabinoid hemp retailer, either directly or indirectly through any other person.

(d) No license application shall be considered for any applicant who is substantially the same as an applicant who has been denied a license within six months of a determination by the office denying such application. In the event an applicant receives two successive license denials, no license application shall be considered for that applicant within two years of the last determination by the office denying a previous application.

(e) The office will prioritize applications from applicants who previously held a valid research partnership agreement with the New York State Department of Agriculture and Markets pursuant to Article 29-A of the New York State Agriculture and Markets Law. All other applications will be reviewed in the order they are received by the office.

(f) For applicants seeking licensure as a cannabinoid hemp processor, the office may provisionally approve the application. Before a cannabinoid hemp processor license is issued, and the applicant can begin extracting or manufacturing, the provisionally approved applicant must first satisfy the following requirements:

(1) if for Extracting and Manufacturing or Manufacturing Only:

(i) a copy of a certificate of occupancy, or it's equivalent, demonstrating compliance with all local building codes; and

(ii) a copy of the approved applicant's qualified third-party GMP certification.

(2) payment of licensure fee as follows:

(i) Cannabinoid Hemp Processor – Extraction and Manufacturing: $3,500;

(ii) Cannabinoid Hemp Processor – Manufacturing Only: $1,000; or

(iii) Cannabinoid Hemp Farm Processer: $300.

(3) proof of sufficient product liability insurance for all manufactured cannabinoid hemp products; and

(4) evidence, to the office's satisfaction, that the applicant will be able to comply with this Part, which may include an onsite inspection.

(g) If a provisionally approved applicant fails to satisfy the requirements in subdivision (f) of this section within six months, the provisional approval will be revoked and the application denied; provided the applicant may request additional time and shall have the opportunity to demonstrate to the office a reasonable documented effort to complete the requirements of subdivision (f) of this section.

(h) Cannabinoid hemp processor licenses shall be valid for two years from the date of issuance of the license.

(i) A cannabinoid hemp processor seeking to terminate its license shall submit a withdrawal notice to the office at least 30 days prior to termination, along with a plan for shutting down operations at the licensed facility. Any licensing fees paid or invoiced prior to notice of withdrawal are not eligible for refund.

(j) Cannabinoid hemp retailer licenses shall be valid for one year from the date of issuance of the license.

(k) Cannabinoid hemp retailer applicants who submitted a completed application to the Department of Health on or before June 1, 2021 may sell cannabinoid hemp products at retail to consumers before having their license approved or denied by the office, provided that the cannabinoid hemp retail applicant adheres to all requirements of this Part.

Section 114.5 License Renewal

(a) An application to renew any license issued under this Part shall be filed with the office not more than 90 days nor less than 30 days prior to the expiration thereof. If a renewal application is not filed at least 30 days prior to the expiration thereof, the office may determine that the license shall expire and become void on such expiration date.

(b) Renewal applications shall be accompanied by a non-refundable application fee and a refundable license fee, as follows:

(1) Cannabinoid Hemp Processor – Extraction and Manufacturing: $1,000 application fee, $3,500 license fee;

(2) Cannabinoid Hemp Processor – Manufacturing Only: $500 application fee, $1,000 license fee; or

(3) Cannabinoid Hemp Farm Processor: $100 application fee, $300 license fee;

(4) Cannabinoid Hemp Retailer: $300 license fee per retail location;

(5) the license fee shall be returned if the licensee's renewal application is not granted.

(c) The application for renewal shall be submitted to the office, in a manner prescribed by the office, and include such information as the office may require.

(d) The office shall determine whether to renew an applicant's license based on the relevant factors in section 114.4 of this Part.

Section 114.6 Transferability, License Amendment and Change in Ownership or Control

(a) Licenses issued under this Part shall be effective only for the licensee and shall specify the following information:

(1) name of the licensee;

(2) address of the real property, or if applicable the online retailer website, where the licensed activities may take place;

(3) date of issuance;

(4) date of expiration;

(5) license number; and

(6) list of activities the licensee is permitted to perform under the license.

(b) Licenses shall not be transferable or assignable without prior written approval of the office including, without limitation, to another licensee. A change in majority ownership or controlling interest in the license or person holding the license, shall constitute a transfer of the license.

(c) To obtain approval from the office for the transfer of a license, a transferee must submit an application to the office, in a manner prescribed by the office, demonstrating an ability to operate the license in compliance with this Part, along with an application fee pursuant to section 114.2 or 114.3, as applicable.

(d) The office may deny an application for transfer of a license if the application fails to demonstrate that the transferee will comply with all of the requirements of this Part, or if the licensee has a record of poor performance, meaning two or more violations pursuant to section 114.17 of this Part, within the past two-years.

(e) A licensee may amend a license to add or delete permitted activities or change the location of a licensed facility by submitting a written request to the office along with an application fee pursuant to sections 114.2 or 114.3 of this Part, as applicable.

(f) A request to add permitted activities shall be reviewed by the office in accordance with section 114.4 of this Part.

Section 114.7 Requirements for Cannabinoid Hemp Processors

(a) All cannabinoid hemp processors shall:

(1) extract hemp extract and/or manufacture cannabinoid hemp products to GMP standards and if applicable for the type of processor license, maintain a qualified third-party certification, to the satisfaction of the office, for the applicable GMP standard(s) for the duration of the license;

(2) maintain standard operating procedures and quality control standards to ensure consistency of hemp extract and/or cannabinoid hemp products, including but not limited to product purity, strength and composition;

(3) maintain sufficient records to demonstrate that any hemp or hemp extract used by the licensee was grown, derived, extracted and transported in accordance with applicable laws and licensing requirements of the jurisdiction(s) from which such hemp or hemp extract was sourced. Such records shall include any pesticides used in the growing of such hemp, date(s) each

shipment was received, adequate chain of custody to demonstrate from whom the licensee purchased such hemp or hemp extract, and certificates of analysis. For hemp received from an out-of-state grower, processors shall also maintain records of the out-of-state grower registration or license number in the respective jurisdiction;

(4) keep all designated extracting and manufacturing areas safe and sanitary, including but not limited to ensuring that such areas are adequately lit, cleaned, smoke-free, and no food is consumed in such areas;

(5) provide all employees performing extraction or manufacturing with adequate training and proper safety equipment;

(6) manufacture cannabinoid hemp products in accordance with section 114.8 of this Part;

(7) test a statistically significant number of cannabinoid hemp products per lot or batch at a third-party testing laboratory meeting all the requirements in section 114.10 of this Part, and maintain a certificate of analysis for all samples tested;

(8) maintain sufficient records pertaining to the calibration and inspection of instruments used in extraction and manufacturing of cannabinoid hemp products;

(9) report, in a frequency and manner prescribed by the office, the total production and sales of the licensee during such reporting period;

(10) ensure the security of the licensed premises to prevent unauthorized individuals from entering the facility and to prevent hemp extract and/or cannabinoid hemp products from being diverted from the facility;

(11) not use synthetic cannabinoids, or Δ8-tetrahydrocannabinol or Δ10-tetrahydrocannabinol created through isomerization, in the extraction or manufacturing of any cannabinoid hemp products;

(12) assign a lot or batch number to each lot of hemp extract or cannabinoid hemp product, extracted or manufactured by a licensee; and

(13) maintain any and all records required by this Part for at least three years and immediately produce such records upon request of the office.

(b) Possession and the intermediate sale of hemp extract by and between licensed cannabinoid hemp processors, is permitted, provided when such extract leaves the licensed premises it is accompanied by a certificate of analysis certifying that the extract is less than five (5) percent THC and a copy of the cannabinoid hemp processor's license, and further provided such hemp extract is only transported intra-state.

(c) Licensees shall monitor complaints from cannabinoid hemp retailers and consumers and have a mechanism in place to notify the licensee's supply chain to recall products when directed by the office or as deemed appropriate by the licensee. Licensees shall notify the office within 24 hours of learning of a serious adverse event.

(d) Licensees shall ensure the proper disposal, beyond reclamation, of any hemp extract or by-product from the extraction and manufacture process with a total Δ9-Tetrahydrocannabinol concentration greater than three-tenths of a percent (0.3%) and which will not be used or subject to further processing. Such disposal shall render the hemp extract or by-product unusable for any intoxicating purpose. Licensees shall maintain records to document and track any Δ9-Tetrahydrocannabinol extracted from hemp or found within hemp extract throughout the extraction and manufacturing process, including records pertaining to the amount used in cannabinoid hemp products and the disposal of all hemp extract, Δ9-Tetrahydrocannabinol or by-product;

(1) licensees shall dispose of any cannabinoid hemp product that is outdated, damaged, deteriorated, contaminated or otherwise deemed not appropriate for sale; and

(2) licensees shall dispose of liquid, chemical and hazardous waste in accordance with applicable federal, state and local laws and regulations.

(e) The office may conduct random sampling and testing of hemp, hemp extract, cannabinoid hemp products, or any solvents, chemicals, or materials used by the licensee, unannounced, at any time during normal business hours of the licensee.

(f) If a cannabinoid hemp processor is authorized to perform extraction, the processor shall:

(1) only extract using methods approved by the office, on the licensed premises, and using employees and equipment sufficient to ensure safe extraction; and

(2) use only those solvents that are approved by the office. Solvent-based extraction must be completed in a commercial, professional grade, closed-loop system capable of recovering the solvent used for extraction.

Section 114.8 Cannabinoid hemp product requirements

(a) All cannabinoid hemp products distributed or offered for retail sale in New York State shall:

(1) be manufactured in accordance with Parts 101, 111 or 117 of Title 21 of the Code of Federal Regulations, as appropriate for the type of product being manufactured and as otherwise determined appropriate by the office in guidance or future regulation.

(2) contain no more than three-tenths of a percent (0.3%) total Δ9-Tetrahydrocannabinol concentration. The office may through future regulation impose a total THC cap for the purpose of protecting public health, which shall include detectable levels of total Δ9-Tetrahydrocannabinol, Δ8-Tetrahydrocannabinol and Δ10-Tetrahydrocannabinol in milligrams per serving and milligrams per package for cannabinoid hemp products based on the product form, volume, number of servings, and ratio of CBD to THC;

(3) not contain liquor, wine, beer, cider or meet the definition of an alcoholic beverage as defined in section 3 of the Alcohol Beverage Control Law;

(4) not contain tobacco or nicotine in the product;

(5) not be in the form of an injectable, inhaler, product including cigarette, cigar or pre-roll, or any other disallowed form as determined by the office;

(6) accurately reflect testing results and not contain less than 80 percent or more than 120 percent of the concentration of total cannabinoid content as listed on the product label;

(7) comply with packaging and labeling standards in section 114.9 of this Part;

(8) be prepackaged and not added to food or any other consumable products at the point of sale;

(9) comply with product testing standards in section 114.10 of this Part; and

(10) not contain synthetic cannabinoids, or cannabinoids created through isomerization, including Δ8-tetrahydrocannabinol and Δ10-tetrahydrocannabinol.

(b) If the cannabinoid hemp product is a food or beverage manufactured under Part 117 of Title 21 Code of Federal Regulations, it shall not contain more than 25 milligrams of total cannabinoids per individually packaged product. If the cannabinoid hemp product is a

supplement manufactured under Part 111 of Title 21 Code of Federal Regulations, it shall not contain more than 3,000 milligram of total cannabinoids per product, with no more than 100 milligrams per individual serving.

(c) If the cannabinoid hemp product contains multiple servings which are not individually wrapped, premeasured, separated or delineated, it shall include a measuring device such as a measuring cap, cup or dropper with the product packaging. Hash marks on the package shall not qualify as a measuring device. This provision shall not apply to flower products.

(d) All inhalable cannabinoid hemp products shall meet the following additional requirements:

(1) be a closed system with a pre-filled disposable cartridge that attaches to a rechargeable battery, or a single-use product that cannot be recharged;

(2) electronic vaporization devices shall have internal or external temperature controls to prevent combustion and have a heating element made of inert material such as glass, ceramic or stainless steel and not plastic or rubber;

(3) except for hemp-derived terpenes, excipients and ingredients must be pharmaceutical grade unless otherwise approved by the office, and shall not include:

(i) synthetic terpenes;

(ii) polyethylene glycol (PEG);

(iii) vitamin E acetate;

(iv) medium chain triglycerides (MCT oil);

(v) medicinal compounds;

(vi) illegal or controlled substances;

(vii) artificial food coloring;

(viii) benzoic acid;

(ix) diketones; and

(x) any other compound or ingredient as determined by the office in regulation;

(4) not contain any flavors or flavoring agents, except for hemp-derived terpenes; and

(5) include an office approved symbol, as set out in future regulation, in a manner that is clear and conspicuous.

Section 114.9 Packaging and labeling of cannabinoid hemp products.

(a) All cannabinoid hemp products distributed or offered for retail sale in New York State shall include the following information on the product label or packaging:

(1) if the cannabinoid hemp product is consumed through ingestion, comply with the requirements in Title 21 Code of Federal Regulations Part 101 and include a nutritional or supplement fact panel that is based on the number of servings within the container;

(2) a list of all ingredients in descending order of predominance by weight in the product;

(3) the number of servings per package or container, including the milligrams per serving of:

(i) CBD;

(ii) "Total THC" or "THC" which for the purposes of product labeling may be rounded and shall include detectable levels of total Δ9-Tetrahydrocannabinol, Δ8-Tetrahydrocannabinol and Δ10-
Tetrahydrocannabinol; and

(iii) any other marketed cannabinoid;

(4) an expiration or best by date if applicable;

(5) a lot or batch number;

(6) the name of the cannabinoid hemp processor or out of state manufacturer, packer or distributor;

(7) a scannable bar code or QR code linked to a downloadable certificate of analysis, or linked to a website where the certificate of analysis can be downloaded;

(8) the state(s) or if outside of the United States of American, country of origin from which hemp used in the product was sourced;

(9) a means for reporting serious adverse events or side effects; and

(10) any other marking, statement or symbol as required by the office in regulation.

(b) No cannabinoid hemp product packaging shall imitate a candy label or use cartoons or other images popularly used to advertise to children or otherwise be marketed to anyone under 18 years of age, or for inhalable cannabinoid hemp products and flower product, to anyone under 21 years of age.

(c) All cannabinoid hemp products shall be packaged in tamper-evident packaging that minimizes oxygen and light exposure to prevent degradation of the product and cannabinoids.

(d) All cannabinoid hemp products shall be accompanied by recommended serving and clear usage instructions.

(e) All cannabinoid hemp products claiming to be “craft” “isolate,” “full spectrum,” “broad spectrum,” or “distillate” shall comply with the applicable definition contained in this Part.

(f) All cannabinoid hemp products offered for retail sale shall include the following warnings on the product label or packaging, in a manner that is clear and conspicuous:

(1) keep out of the reach of children;

(2) that the product is derived from hemp and may contain THC which could result in a failed drug test. Provided however, this warning may be omitted for cannabinoid hemp products that are: topically applied; made exclusively using an “isolate;” or made from “broad spectrum” hemp extract ;

(3) that the product has not been evaluated by the Food and Drug Administration for safety or efficacy;

(4) those who are pregnant or nursing should consult their healthcare provider before use; and

(5) if the product is an inhalable cannabinoid hemp product, a warning stating that smoking or vaporizing is hazardous to your health.

(g) No information required to be listed on cannabinoid hemp product labeling or packaging in accordance with this section shall be smaller than 4.5-point font.

Section 114.10 Laboratory testing requirements for cannabinoid hemp

(a) For purposes of this Section, the following terms shall have the following meanings:

(1) “Accreditation body” means an impartial non-profit organization that operates in conformance with the International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) standard 17011 and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for Testing.

(2) “Scope of accreditation” means a document issued by an accreditation body that attests to the laboratory’s competence to carry out specific testing and analysis.

(3) “Testing laboratory” means an independent, third-party laboratory, contracted by a cannabinoid hemp processor to test cannabinoid hemp products.

(b) To be recognized as a testing laboratory for purposes of testing cannabinoid hemp products as required by this Part, a laboratory must either be approved to test medical marijuana pursuant

to Section 55-2.15 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York, Article 6 of the Cannabis Law, or meet all of the following minimum requirements:

(1) maintain ISO/IEC 17025 accreditation for the premises and for the testing of one or more of the following:

(i) Cannabinoids;

(ii) Heavy metals;

(iii) Microbial impurities;

(iv) Mycotoxins;

(v) Residual pesticides;

(vi) Residual solvents and processing chemicals; or

(vii) If tested, terpenoids.

(2) maintain a valid scope of accreditation, issued by an accreditation body, that attests to the laboratory's competence to perform testing of one or more analytes listed in subdivision (b)(1) of this section.

(3) maintain method validation reports for all testing performed; and

(4) maintain standard operating procedures for the sampling of cannabinoid hemp products.

(c) Cannabinoid hemp processors shall retain, and make available to the office upon request, all records associated with their testing laboratory's ISO/IEC 17025 accreditation, scope of accreditation, method validation reports and standard operating procedures for the sampling of cannabinoid hemp products, as required by this section.

(d) Cannabinoid hemp products shall be considered adulterated and shall not be sold within New York State, if contaminants are detected at levels greater than provided for by the office in this Part or issued in further guidance.

(e) The office shall have the ability to impose additional testing requirements including but not limited to, testing for additional analytes, setting stricter contaminant limits and mandating the use of specific sampling methodologies per lot or batch manufactured.

(f) Pesticide Limits. The following list of contaminants does not constitute authorization to use or apply any of the following during hemp cultivation or processing. If a pesticide is identified

that is not listed here, the method limit of quantitation should be considered the maximum residue level for the unlisted pesticide:

1. Abamectin, 300 parts per billion.

2. Acephate, 3,000 parts per billion.

3.Acequinocyl, 2,000 parts per billion.

4. Acetamiprid, 3,000 parts per billion.

5. Aldicarb, 100 parts per billion.

6. Azoxystrobin, 3,000 parts per billion.

7. Bifenazate, 3,000 parts per billion.

8. Bifenthrin, 500 parts per billion.

9. Boscalid, 3,000 parts per billion.

10. Captan, 3,000 parts per billion.

11. Carbaryl, 500 parts per billion.

12. Carbofuran, 100 parts per billion.

13. Chlorantraniliprole, 3,000 parts per billion.

14. Chlordane, 100 parts per billion.

15. Chlorfenapyr, 100 parts per billion.

16. Chlormequat chloride, 3,000 parts per billion

17. Chlorpyrifos, 100 parts per billion.

18. Clofentezine, 500 parts per billion.

19. Coumaphos, 100 parts per billion.

20. Cyfluthrin, 1,000 parts per billion.

21. Cypermethrin, 1,000 parts per billion.

22. Daminozide, 100 parts per billion.

23. DDVP (Dichlorvos), 100 parts per billion.

24. Diazinon, 200 parts per billion.

25. Dimethoate, 100 parts per billion.

26. Dimethomorph, 3,000 parts per billion.

27. Ethoprop(hos), 100 parts per billion.

28. Etofenprox, 100 parts per billion.

29. Etoxazole, 1,500 parts per billion.

30. Fenhexamid, 3,000 parts per billion.

31. Fenoxycarb, 100 parts per billion.

32. Fenpyroximate, 2,000 parts per billion.

33. Fipronil, 100 parts per billion.

34. Flonicamid, 2,000 parts per billion.

35. Fludioxonil, 3,000 parts per billion.

36. Hexythiazox, 2,000 parts per billion.

37. Imazalil, 100 parts per billion.

38. Imidacloprid, 3,000 parts per billion.

39. Kresoxim-methyl, 1,000 parts per billion.

40. Malathion, 2,000 parts per billion.

41. Metalaxyl, 3,000 parts per billion.

42. Methiocarb, 100 parts per billion.

43. Methomyl, 100 parts per billion.

44. Methyl parathion, 100 parts per billion.

45. Mevinphos, 100 parts per billion.

46. Myclobutanil, 3,000 parts per billion.

47. Naled, 500 parts per billion.

48. Oxamyl, 500 parts per billion.

49. Paclobutrazol, 100 parts per billion.

50. Pentachloronitrobenzene, 200 parts per billion.

51. Permethrin, 1,000 parts per billion.

52. Phosmet, 200 parts per billion.

53. Piperonyl butoxide, 3,000 parts per billion.

54. Prallethrin, 400 parts per billion.

55. Propiconazole, 1,000 parts per billion.

56. Propoxur, 100 parts per billion.

57. Pyrethrins, 1,000 parts per billion.

58. Pyridaben, 3,000 parts per billion.

59. Spinetoram, 3,000 parts per billion.

60. Spinosad A & D, 3,000 parts per billion.

61. Spiromesifen, 3,000 parts per billion.

62. Spirotetramat, 3,000 parts per billion.

63. Spiroxamine, 100 parts per billion.

64. Tebuconazole, 1,000 parts per billion.

65. Thiacloprid, 100 parts per billion.

66. Thiamethoxam, 1,000 parts per billion.

67. Trifloxystrobin, 3,000 parts per billion.

(g) Residual Solvent Limits.

1. 1,2-Dichloroethane, 5 parts per million

2. 1,1-Dichloroethene, 8 parts per million

3. Acetone, 5,000 parts per million

4. Acetonitrile, 410 parts per million

5. Benzene, 2 parts per million

6. Butane, 2,000 parts per million

7. Chloroform, 60 parts per million

8. Ethanol, 5,000 parts per million

9. Ethyl Acetate, 5,000 parts per million

10. Ethyl Ether, 5,000 parts per million

11. Ethylene Oxide, 5 parts per million

12. Heptane, 5,000 parts per million

13. Hexane, 290 parts per million

14. Isopropyl Alcohol, 5,000 parts per million

15. Methanol, 3,000 parts per million

16. Methylene Chloride, 600 parts per million

17. Pentane, 5,000 parts per million

18. Propane, 5,000 parts per million

19. Toluene, 890 parts per million

20. Trichloroethylene (1,1,2-Trichloroethene), 80 parts per million

21. Xylenes, Total (ortho-, meta-, para-), 2170 parts per million

(h) Metals Limits.

1. Cadmium, 0.5 micrograms/gram for cannabinoid hemp products intended for ingestion. 0.2 micrograms/gram for cannabinoid hemp products intended for inhalation.

2. Lead, 1.0 micrograms/gram for cannabinoid hemp products intended for ingestion. 0.5 micrograms/gram for cannabinoid hemp products intended for inhalation.

3. Arsenic, 1.5 micrograms/gram for cannabinoid hemp products intended for ingestion. 0.2 micrograms/gram for cannabinoid hemp products intended for inhalation.

4. Mercury, 1.5 micrograms/gram for cannabinoid hemp products intended for ingestion. 0.1 micrograms/gram for cannabinoid hemp products intended for inhalation.

(i) Biological Limits.

1. Shiga toxin-producing Escherichia coli (STEC E. coli) and other pathogenic E. coli, none detected in 1 gram.

2. Salmonella, none detected in 1 gram.

3. Total plate count for aerobic bacteria, $<10^4$ CFUs/gram.

4. Total yeast and mold, $<10^3$ CFUs/gram.

(j) Mycotoxin Limits.

1. Total Aflatoxin (B1, B2, G1, G2), 20 parts per billion.

2. Ochratoxin A, 20 parts per billion.

(k) Cannabinoid Limits. The total Δ9-Tetrahydrocannabinol concentration for cannabinoid hemp products shall not exceed three-tenths of a percent (0.3%). If a cannabinoid hemp product fails, the processor may elect to re-formulate the failing batch to reduce the total Δ9-Tetrahydrocannabinol of the batch to not more than three-tenths of a percent (0.3%) total Δ9-Tetrahydrocannabinol. If the re-formulated batch still exceeds the three-tenths of a percent (0.3%) total Δ9-Tetrahydrocannabinol the processor shall destroy the batch in compliance with subdivision (d) of section 114.7 of this Part.

(l) If a cannabinoid hemp product is found to contain levels of any pathogen, toxicant, residual solvent, metal, or pesticide not enumerated in this section or by New York State law, then the product shall not be sold in New York State.

Section 114.11 Requirements for cannabinoid hemp retailers

(a) Cannabinoid hemp retailers shall only sell cannabinoid hemp products manufactured, packaged, labeled and tested in accordance with this Part.

(b) Cannabinoid hemp retailers shall not offer or sell any cannabinoid hemp product clearly labeled or advertised for the purpose of smoking, or in the form of a cigarette, cigar, or pre-roll, or packaged or combined with other items designed to facilitate smoking such as rolling papers or pipes. Retailers shall have sufficient safeguards in place to verify that an individual presenting or submitting proof of age for an inhalable cannabinoid hemp product or flower product matches the identification and is 21 years of age or older.

(c) Cannabinoid hemp retailers shall post, visible to consumers, any and all signs or posted placards required by the office, including posting of the cannabinoid hemp retail license issued by the office, in a conspicuous location on the premises of each retail location.

(d) Cannabinoid hemp products shall be displayed in a manner that distinguishes them from non-cannabinoid hemp products, to aide consumers in locating cannabinoid hemp products and avoid accidental purchase or consumption.

(e) Cannabinoid hemp retailers shall maintain sufficient records of where cannabinoid hemp products were purchased from for the license period, including the name of the cannabinoid hemp processor if applicable, and the wholesaler or permitted distributor if applicable.

(f) The office may inspect any retail location offering cannabinoid hemp products. This inspection may include taking samples of cannabinoid hemp products to ensure compliance with all the requirements of this Part.

Section 114.12 Advertising requirements

(a) An advertisement for a cannabinoid hemp product, cannabinoid hemp processor or cannabinoid hemp retailer shall not:

(i) make any false or misleading claims or statements;

(ii) contain claims that cannabinoid hemp or a cannabinoid hemp product can, or is intended to, diagnose, cure, mitigate, treat, or prevent disease;

(iii) lead a reasonable person to believe that a cannabinoid hemp product is adult-use cannabis, marihuana, medical cannabis, or medical marihuana, or that a licensee is authorized to sell or dispense adult-use cannabis, marihuana, medical cannabis, or medical marihuana, as those terms are defined in Section 3 of the Cannabis Law and Article 33 of the Public Health Law;

(iv) have the purpose or effect of targeting or appealing to anyone under 21 years of age for inhalable cannabinoid hemp products or flower product. The use of images of children or minors consuming the product and the use of words, a design or brand that resembles a product that is commonly associated with children or minors or marketed to children or minors, is prohibited.

Section 114.13 New York Hemp Product

(a) A New York Hemp Product is a cannabinoid hemp product exclusively grown in New York State and processed in New York State by processors that are licensed under this Part and that demonstrate compliance with all requirements enumerated by the office;

(b) The office may establish standards and requirements above and beyond those established in this Part and use such standards and requirements to certify products as New York Hemp Product.

(c) The office may revoke a cannabinoid hemp product's status as certified New York Hemp Product, without a hearing, if it has reason to believe that such product no longer meets one or more of the standards or requirements established by the office.

(d) No cannabinoid hemp product sold in New York state may use the term "New York Hemp Product" or hold itself out as being New York Hemp Product, or approved or certified by the office in any way, unless such product has been certified by the office pursuant to this section, in which case the cannabinoid hemp processor and cannabinoid hemp retailer may portray such product(s) as being certified New York Hemp Product. A violation of this subdivision constitutes grounds for suspension or revocation of a license.

Section 114.14 General prohibitions

(a) No licensee shall engage in any activity relating to the processing, packaging, labeling manufacturing, extracting, distributing, selling or laboratory testing of cannabinoid hemp extract or cannabinoid hemp that does not comply with the requirements of Article 5 of the Cannabis Law and this Part.

(b) No person shall extract hemp extract or manufacture cannabinoid hemp products in New York State unless licensed to engage in such activity by the office or otherwise authorized by the United States food and drug administration.

(c) Hemp extract shall be manufactured into cannabinoid hemp product before being offered for retail sale and shall not be distributed or sold directly to consumers within the state.

(d) No cannabinoid hemp product shall be distributed or offered for retail sale in New York State unless:

(1) it complies with the processing, packaging, labeling and testing requirements pursuant to sections 114.8, 114.9 and 114.10 of this Part; and

(2) is sold by a cannabinoid hemp retailer licensed under this Part;

(e) No person shall transport hemp extract within the state, unless:

(1) it is in a fully enclosed vehicle or container; and

(2) accompanied by a manifest or proof of ownership, documenting the name, physical address, lot or batch number, certificate of analysis and license number of the originating licensed cultivator or processor, and the name and physical address of the recipient of the delivery when transporting between non-adjoining facilities. When hemp extract is being transported to a laboratory for testing, a certificate of analysis is not required to accompany the shipment.

(f) Hemp extract shall not be shipped or transported into New York State unless:

(1) it is in a fully enclosed vehicle or container;

(2) accompanied by proof of origin with a hemp cultivation or processor license number, or equivalent, from the jurisdiction of origin; and

(3) accompanied by a certificate of analysis showing that the hemp extract has a total Δ9-Tetrahydrocannabinol of no more than three tenths of a percent (0.3%).

(g) No person shall distribute cannabinoid hemp products manufactured out of state, to a cannabinoid hemp retailer within New York State, unless permitted pursuant to section 114.18 of this Part.

Section 114.15 Cannabinoid hemp processor prohibitions

(a) No cannabinoid hemp processor may transfer a license issued under this Part without prior written approval of the office.

(b) No cannabinoid hemp processor shall manufacture a cannabinoid hemp product that is a potentially hazardous food, as defined by Section 14-1.31 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York.

(c) No cannabinoid hemp processor may conduct final product testing for the licensee's own products to meet the testing requirements of Section 114.10 of this Part. Nothing in this Part prohibits a cannabinoid hemp processor from performing internal testing for research and product development or for quality assurance prior to final product testing by a third-party laboratory.

(d) No cannabinoid hemp processor may sell cannabinoid hemp products to consumers for final retail sale without first obtaining a cannabinoid hemp retail license.

(e) No cannabinoid hemp processor shall sell hemp extract to anyone in New York State, unless such person is licensed as a cannabinoid hemp processor under this Part, registered as a registered organization under Section 3365 of the Public Health Law or Article 3 of the Cannabis Law.

Section 114.16 Cannabinoid hemp retailer prohibitions

(a) No cannabinoid hemp retailer shall offer or sell cannabinoid hemp products in the form of an inhalable cannabinoid hemp product or flower product to anyone under 21 years of age.

(b) No cannabinoid hemp retailer shall sell a cannabinoid hemp product that is a potentially hazardous food, as defined by Section 14-1.31 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York.

(c) Cannabinoid hemp retailers shall only offer and sell cannabinoid hemp products that meet all of the standards and requirements of sections 114.8, 114.9 and 114.10 of this Part.

(d) Cannabinoid hemp retailers shall not offer or sell any cannabinoid hemp product to be added to food or other consumable products at the point of sale.

Section 114.17 Penalties

(a) Licensees under this Part shall comply with all applicable laws, rules and regulations as it relates to such licensure.

(b) Failure to comply with a requirement of Article 5 of the Cannabis Law or this Part may be punishable by a civil penalty, as follows:

(i) a fine of up to $1,000 for a first violation;

(ii) a fine up to $5,000 for a second violation within three-years; or

(iii) a fine up to $10,000 for a third violation and each subsequent violation thereafter, within a three-year period.

(c) Where a licensee willfully violates, refuses or neglects to comply with one or more sections of this Part, the office may limit, suspend, revoke or annul a license after providing notice and an opportunity for a hearing to the licensee. However, a license may be temporarily limited, suspended, revoked or annulled without a hearing for a period not to exceed 30-days, upon notice to the licensee, following a finding by the office that the public health, safety or welfare is in imminent danger.

(d) A licensee who negligently violates this Part three times in a five-year period shall be ineligible to process or sell cannabinoid hemp for a period of five years beginning on the date of the third violation. The office, for good cause shown, may choose to impose a lesser penalty.

Section 114.18 Cannabinoid hemp permits

(a) The office may issue cannabinoid permits expressly authorizing a permittee to conduct one or more of the following activities:

(1) distribute cannabinoid hemp products manufactured out of state, to cannabinoid hemp retailers within New York State;

(2) deliver cannabinoid hemp products from a cannabinoid hemp retailer to consumers;

(3) sell at retail cannabinoid hemp products for a limited duration;

(4) continue operations for persons holding a valid CBD processor research partnership agreement with the New York State Department of Agriculture and Markets pursuant to Article 29-A of the New York State Agriculture and Markets Law;

(5) any other activity as determined by the Cannabis Control Board.

(b) Applicants for a cannabinoid hemp permit must apply on a form prescribed by the office and submit a $100 application fee and permit fee as may be set by the office.

(c) Permits issued pursuant to this section shall be valid for one year from the date of issuance, unless the office prescribes a shorter time period for expiration.

Section 114.19 Severability.

The provisions of this Part are severable. If any provision of this Part is found to be invalid, or if any application of this Part to any person or circumstance is found to be invalid, the invalidity shall not affect any other provisions or applications which can be given effect without the invalid provision or application.

Section 114.20 Incorporation by reference.

The provisions of the Code of Federal Regulations which have been incorporated by reference in this Subpart have been filed in the Office of the Secretary of State of the State of New York, the publication so filed being the booklet entitled: Code of Federal Regulations, Title 21, Parts 101, 111, and 117, revised as of April 1, 2012, June 25, 2007, and January 1, 2019 respectively, published by the Office of the Federal Register, National Archives and Records Administration. The regulations incorporated by reference may be examined at the Records Access Office, New York State Office of Cannabis Management, Harriman State Office Building Campus, Albany, New York, 12207 or can be directly obtained from the Superintendent of Documents, US Government Printing Office, Washington, D.C. 20402.

Section 114.21 Effective date

(a) The provisions of this Part are effective upon publication in the State Register; provided, however, that sections 114.9 and 114.10 of this Part shall not become effective until April 25, 2021.

(b) Notwithstanding subdivision (a) of this section, a licensed cannabinoid hemp retailer may continue to possess, transport, and sell cannabinoid hemp products in the retailer's inventory before the effective date of this Part, unless the cannabinoid hemp product:

(1) is unsafe for consumption based on the presence or quantity of heavy metals, pesticides, harmful microorganisms, or residual solvents;

(2) has a Δ-9 tetrahydrocannabinol concentration of more than 0.3 percent;

(3) is a flower product clearly labeled or advertised for the purpose of smoking or in the form of a cigarette, cigar or pre-roll or otherwise packaged or combined with other items designed to facilitate smoking such as rolling papers or pipes; or

(4) contains or was manufactured with Δ8-tetrahydrocannabinol or Δ10-tetrahydrocannabinol created through isomerization.